

SciReg, Inc.
Science and Regulatory Consultants

January 6, 2017

Document Processing Desk (DCI/AD)
Attn: Reevaluation Team Leader, PM 36
U.S. EPA (7510P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

Re: DCI ID # GDCI-107401-1635
- 90-day response
- IndusCo, Ltd. (EPA Co. No. 53053)

Dear Sir or Madam:

On behalf of IndusCo, Ltd., SciReg, Inc. is submitting the 90-day response to the generic DCI for 1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride (ID # GDCI-107401-1635) for EnviroSystems ProShield 5000 (EPA Reg No. 53053-21), EnviroSystems BioShield 150 (EPA Reg No. 53053-22), EnviroSystems BioShield 50 (EPA Reg No. 53053-23), EnviroSystems BioShield 75 (EPA Reg No. 53053-24), EnviroSystems BioShield 7200 (EPA Reg No. 53053-25), EnviroSystems ProShield 3651 I (EPA Reg No. 53053-26), EnviroSystems ProShield 3651 D (EPA Reg No. 53053-27), and EnviroSystems ProShield 5000 D (EPA Reg No. 53053-28).

The Data Call-In and Requirements Status and Registrant's Response forms are enclosed. IndusCo has entered into an agreement with the Silane Quats Task Force to share in the cost to develop the required data [see enclosed letter from Catherine Rice (Steptoe & Johnson LLP)].

If you have any questions, please contact me at 703-494-6500 or cbell@SciReg.com.

Sincerely,



Cinda L. Bell, MS
Regulatory Specialist

Enclosure

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address INDUSCO LTD 12733 DIRECTOR'S LOOP WOODBIDGE, VA 22192		2. Case # and Name 3148 - 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride Chemical # and Name: 107401 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride		3. Date and Type of DCI and Number 29-Sep-2016 GENERIC ID # GDCL-107401-1635	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
53053-21			Yes	N/A	N/A
53053-22			Yes	N/A	N/A
53053-23			Yes	N/A	N/A
53053-24			Yes	N/A	N/A
53053-25			Yes	N/A	N/A
53053-26			Yes	N/A	N/A
53053-27			Yes	N/A	N/A
53053-28			Yes	N/A	N/A
8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.					9. Date
Signature and Title of Company's Authorized Representative <u>Cinda K. Bell, Regulatory Specialist</u>					1/16/17
10. Name of Company <u>SciReg, Inc. - Agent for Indus Co, Ltd.</u>					11. Phone Number <u>703-494-6500</u>

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address INDUSCO LTD 12733 DIRECTOR'S LOOP WOODBIDGE, VA 22192		2. Case # and Name 3148 - 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride Chemical # and Name: 107401 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride			3. Date and Type of DCI and Number 29-Sep-2016 GENERIC ID # GDCL-107401-1635				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Applicator Exposure Data Requirements (Conventional Chemical)								
875.1300	Inhalation exposure--outdoor (2, 14)	Y				BB,X,Y,DD,CC,T,Z,V,U	TEP	24	9
875.1400	Inhalation exposure--indoor (2, 14)	Y				BB,X,Y,DD,CC,T,Z,V,U	TEP	24	9
875.1700	Product Use Information	N				BB,X,Y,DD,CC,T,Z,V,U	TEP	12	2
	Environmental Fate Data Requirements (Conventional Chemical)								
835.1230	Sediment and soil absorption/desorption for parent and degradates (6, 13)	N				BB,X,Y,DD,CC,T,Z,V,U	TGAI or PAIRA	12	9
835.4100	Aerobic soil metabolism (6, 13)	N				BB,X,Y,DD,CC,T,Z,V,U	TGAI, PAIRA	24	9
835.4400	Anaerobic aquatic metabolism (6, 13)	N				BB,X,Y,DD,CC,T,Z,V,U	TGAI or PAIRA	24	9
	Nontarget Plant Protection Data Requirements (Conventional Chemical)								
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine, imprisonment or both under applicable law.							11. Date		
Signature and Title of Company's Authorized Representative <i>Cinda H. Bell, Regulatory Specialist</i>							1/6/17		
12. Name of Company <i>SciReg, Inc. - Agent for IndusCo, Ltd.</i>							13. Phone Number <i>703-494-6500</i>		

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address INDUSCO LTD 12733 DIRECTOR'S LOOP WOODBIDGE, VA 22192		2. Case # and Name 3148 - 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride Chemical # and Name: 107401 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride			3. Date and Type of DCI and Number 29-Sep-2016 GENERIC ID # GDCI-107401-1635				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Nontarget Plant Protection Data Requirements (Conventional Chemical)								
850.4400	Aquatic Plant Toxicity Using Lemna spp (1, 8)	N				BB,X,Y,DD,CC,T,Z,V,U	TGA I or TEP	12	9
	Toxicology Data Requirements (Conventional Chemical)								
870.3465	90-day inhalation toxicity (2)	N				BB,X,Y,DD,CC,T,Z,V,U	TGA I	24	9
870.3700	Prenatal developmental toxicity study (9)	N				BB,X,Y,DD,CC,T,Z,V,U	TGA I	24	9
870.3800	Reproduction and fertility effects (4, 9)	N				BB,X,Y,DD,CC,T,Z,V,U	TGA I	48	9
850.4500	Algal Toxicity (1, 7)	N				BB,X,Y,DD,CC,T,Z,V,U	TGA I	12	9
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity (1, 7, 8)	N				BB,X,Y,DD,CC,T,Z,V,U	TGA I or TEP	12	9
SS-1362	Special Study: Leaching study from roofing shingles and fascia board (3, 5, 13, 14)	Y				BB,X,Y,DD,CC,T,Z,V,U	TGA I	12	2

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address INDUSCO LTD 12733 DIRECTOR'S LOOP WOODBRIDGE, VA 22192		2. Case # and Name 3148 - 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride Chemical # and Name: 107401 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride				3. Date and Type of DCI and Number 29-Sep-2016 GENERIC ID # GDCI-107401-1635			
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
SS-1363	Special Study: Whole sediment: chronic invertebrates, 2 species, freshwater (Hyalloa azteca and Chironomus dilutus) (1, 10, 11, 14)	Y				BB,X,Y,DD,CC,T,Z,V,U	TGAI	12	9
SS-1366	Special Study: Whole sediment: chronic invertebrates, marine (Leptocheirus plumulosus) (1, 12, 14)	Y				BB,X,Y,DD,CC,T,Z,V,U	TGAI	12	9

Catherine Rice
202 429 3803

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
202 429 3000 main
www.step toe.com



January 6, 2017

Jessica Bailey
Chemical Review Manager
Regulatory Management Branch II
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

Subject: Silane Quats Task Force
Response to Trimethoxysilyl Quaternary Ammonium Chloride GDCI

Dear Ms. Bailey:

Six current registrants have taken the first steps in creating a Silane Quat Task Force ("Task Force") to address two actives associated with the Trimethoxysilyl Quaternary Ammonium Chloride GDCIs¹:

- 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride (107401); and
- 1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride (107403).

As you are probably aware, the chemistry associated with these quats is rather unique since the "trimethoxysilyl quats undergo a chemical reaction which leads to the formation of trihydroxysilyl quats."² As a result of this reaction, MUPs contain the trimethoxy quat but the associated end-use products contain the trihydroxy quat.

All six registrants (refer to Attachment A) in the Task Force are MUP registrants. Some of these registrants also have end-use products.

¹ The one registrant 1-Tetradecanaminium, N, N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride (107409) products was contacted; however, there was no follow-up response.

² Per the September 2007 Reregistration Eligibility Decision for Trimethoxysilyl Quaternary Ammonium Chloride Compounds.

Path Forward

All six members of the Task Force have discussed this DCI and are in agreement on the following testing strategy:

Option 2 – Agreement to Cost Share (Data to be developed by the Task Force)

- 875.1700 – Product Use Data
- SS-1362 – Special Study: Leaching study from roofing shingles and fascia board

Option 9 - Request for a Waiver of Data:

One of our member companies does have some leaching data and while it cannot be submitted to address SS-1362, it indicates that once the end-use products are applied, the quat does not migrate. The task force believes that the data generated under SS-1362 will demonstrate that the quat does not migrate and thus, will support waiving the following environmental testing requirements:

Environmental fate

- 835.1230 - Sediment and soil adsorption/ desorption
- 835.4100 – Aerobic soil metabolism
- 835.4400 - Anaerobic aquatic metabolism

Ecological effects

- 850.4400 – Aquatic Plant toxicity
- 850.4500 – Algal toxicity
- 850.4550 – Cyanobacterial toxicity

Health effects (per footnote 9)

- 870.3700 – Prenatal developmental toxicity
- 870.3800 – Reproduction and fertility effects

Special studies

- SS-1363 – Special Study: Whole sediment: chronic invertebrates freshwater
- SS-1366 – Special Study: Whole sediment: chronic invertebrates marine

Separate from above, the Task Force is requesting a waiver from the inhalation and exposure studies based a combination of required personnel protective equipment and the magnitude and duration of exposure from the labeled uses. This rationale will be used to waive the following three studies:

- 870.3465 – 90-day inhalation study
- 875.1300 – Inhalation exposure (outdoor)
- 875.1400 – Inhalation exposure (indoor)

Each member of the Task Force will be including this letter as part of their 90-day response.

* * *

Silane Quat Task Force
January 6, 2017
Page 3



Please let me know if you have any questions about the Task Force.

Sincerely,

A handwritten signature in black ink, appearing to read "Catherine Rice". The signature is fluid and cursive, with a prominent "C" and a long, sweeping underline.

Catherine Rice
Manager, Silane Quat Task Force

Appendix A: Silane Quat Task Force
(as of December 22, 2016)

Aquagenics Technologies

2764 Golfview Dr
Naperville, IL 60540
EPA Company Number: 60504

Barr Brands International, Inc.

11400 Vanstory Drive
Huntersville, NC 28078
EPA Company Number: 64881 (AEGIS), 4091 (W.M. Barr & Company)

Gelest, Inc.

11 East Steel Road
Morrisville, PA 19067
EPA Company No. 83019

IndusCo, Ltd.

2319 Joe Brown Dr.
Greensboro, NC 27405
EPA Company Number: 53053.

Unelko Corporation

14641 N. 74th Street
Scottsdale, AZ 85260
EPA Company Number: 71973

Vitec Specialty Chemicals Limited

Wrath Business Centre, Wrath Road
Bury, Lancashire BL9 9TB
United Kingdom
EPA Company No. 85348